OMB 0910-0452
SUPPORTING STATEMENT

GUIDANCE FOR INDUSTRY ON HOW TO USE E-MAIL TO SUBMIT A REQUEST FOR A MEETING OR TELECONFERENCE TO THE OFFICE OF NEW ANIMAL DRUG EVALUATION

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

As part of NAD development, sponsors often meet with CVM scientists to formulate a rational approach to studies to be conducted and to discuss how to meet the statutory requirements for drug approval under Section 512 of the Federal Food, Drug, and Cosmetic Act. Requests for meetings and teleconferences about NAD submissions are currently submitted on paper copy to CVM. This guidance provides instructions to new animal drug sponsors (sponsors) on how to submit a request for a meeting or teleconference about a new animal drug submission as an e-mail attachment by internet. This final guidance implements provisions of the Government Paperwork Elimination Act (GPEA) and is part of CVM's initiative to provide a method for paperless submissions.

The information collection requirement(s) for which we request OMB approval are:

FDA Form 3489 - Reporting - Request for a Meeting or Teleconference

2. Purpose and Use of the Information

CVM holds meetings and/or teleconferences to assist sponsors with NAD submissions and general questions. Such meetings and teleconferences are a courtesy to sponsors initiated at their request. Currently, meeting and teleconference requests are submitted to CVM on paper. CVM would like to allow sponsors to request meetings and teleconferences in a manner more efficient and time saving to them. This guidance will give sponsors the option to submit a request for a meeting or teleconference as an e-mail attachment by the Internet.

3. Use of Information Technology and Burden Reduction

In the Federal Register of March 20, 1997 (62 FR 13430), the FDA published the Electronic Records, Electronic Signatures final regulation. This regulation (21 CFR 11) provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. This rule also established public docket number 97S-0251 to provide a permanent location for a list of the documents or parts of the document that are acceptable for submission in electronic form without paper records and the agency units to which

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such submissions may be made. CVM will identify electronic submission of requests for meetings and teleconferences in this public docket as a submission type which may be made in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

This information is not collected by any other Agency in the Government. The information collection required as a result of 21 CFR 511.1(b)(5) does not duplicate any other information collection.

5. Impact on Small Business or Other Small Entities

There is no impact on small business or other small entitities.

6. Consequences of Collecting the Information Less Frequently

The information required under these regulations must be developed for each meeting or teleconference to the Office of New Animal Drug Evaluation. There is no time schedule for information collection. The frequency is set by the manufacturer production schedule.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The reporting requirements are consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In the **Federal Register** June 29, 2000 (65 FR 40108), the FDA announced the availability of this guidance as a draft document and requested public comment on the proposed collection of information. No comments were received in response to this notice. However, comments regarding the content or format of the guidance document may be submitted to the FDA at any time. The agency will periodically review comments received and incorporate any comments as appropriate.

9. Explanation of Any Payment or Gifts to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

During working hours, only FDA employees have access to the computer files and database on a need to know basis. During duty and non-duty hours building security is provided through a contract with a private protection agency. None of these provisions bar the release of the confidential information if subpoenaed by a court of law. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act. Further, under the terms of the Freedom of Information Act, the sponsor's name, address, and phone number reported on FDA Form 3489 cannot be made available to a public request.

11. Justification for Sensitive Questions

This information does not contain questions pertaining to sex behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

CVM used a wage rate of $35.00 per hour, and multiplied times the total hour burden estimated above (116 hours), the total cost burden to respondents is $4,060 (116 hours X $35/hour).

Table 1 ESTIMATED ANNUAL REPORTING BURDEN 1

FDA Form No	No. of Respondents	Annual Frequency per Respondents	Total Annual Responses	Hours per Response	Total Hours
3489	190	.88	168	0.69	116

1 There are no capital costs or operating anfd maintenance cost associated with this collection of information

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

There are no additional cost associated with this collection of information

14. Annualized Cost to the Federal Government

The cost to the federal government to receive and file notices (paper copy or e-mail) would be the essentially the same cost of burden to industry. A wage rate of $35.00 per hour is used and multiplied times the total hour burden estimated above (116 hours), the total cost to the Federal government is $4,060 (116 hours X $35/hour).

15. Explanation of Program Changes or Adjustments

New Program – No changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.